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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,902	07/02/2002	Nikolai Vladimirovich Bovin	9286-7	7167

20792 7590 01/25/2006

MYERS BIGEL SIBLEY & SAJOVEC
PO BOX 37428
RALEIGH, NC 27627

EXAMINER

MAIER, LEIGH C

ART UNIT PAPER NUMBER

1623

DATE MAILED: 01/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/019,902	Applicant(s) BOVIN ET AL.	
	Examiner Leigh C. Maier	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,8-12,14-16,18,20,23,27 and 28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,8-12,14-16,18,20,23,27 and 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 5, 2005 has been entered.

Claims 1, 10, 12, 15, 18, 23, 27, and 28 have been amended. Claims 1-6, 8-12, 14-16, 18, 20, 23, 27, and 28 are pending. Any rejection or objection not specifically repeated has been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112 – 2nd paragraph

Claims 1-6, 8-12, 14-16, 18, 20, 23, 27, and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to compounds and the use thereof. The compounds (1) comprise "a ligand suitable for specific bonding to a receptor" and (2) form aggregates. The compounds clearly have other limitations, but these are the ones of concern with respect to indefiniteness.

Regarding limitation (1), the specification identifies a number of ligands contemplated for the variable "R." However, there remains an enormous group of entities which are ligands

Art Unit: 1623

that have known receptors, as well as a potentially even larger group with yet *undiscovered* receptors.

Regarding limitation (2), it was noted previously that Tuzikov has reported that claims that are embraced by the structural formula of the claims do not form aggregates. Applicant has responded that these compounds “do not associate under particular conditions, may and can take place under other conditions that can be determined through routine experimentation.” Applicant has further stated that a compound, disclosed in the specification as not forming aggregates, “has been demonstrated to associate in non-aqueous solutions or in water on the virus surface.”

In the instant case, for example, one of ordinary skill may have a compound embraced by the instant formula that demonstrates no apparent aggregation formation. However, it would appear that this artisan would be required to prove a negative to avoid infringement. It is not clear how one of ordinary skill is to know when they have tried enough conditions to prove non-aggregation. Furthermore, say an infinite number of conditions are tried, still with no sign of aggregation, how is the artisan to know about the yet undiscovered receptor to which his compound binds and in whose presence said compound forms an aggregate?

The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent. In view of the forgoing, the instant claims do not meet this requirement.

Claim Rejections - 35 USC § 112 – 1st paragraph

Claims 1-6, 8-12, 14-16, 18, 20, 23, 27, and 28 are again rejected under 35 U.S.C. 112, first paragraph as set forth in the previous Office action, with some revision as set forth herein. As noted previously, the specification is not enabling for the full scope of compounds (limited to those wherein $X=CH_{4-m}$ at this stage of examination) encompassed by the structural formula recited in the claims.

Applicant's arguments filed October 5, 2005 have been fully considered but they are not entirely persuasive.

With respect to the compounds, per se, specifically the structure of the "K" moiety, the examiner is persuaded that the compounds, as amended, would be enabled for $k=5-100$.

The compounds would also be enabled for the ligands (R) recited in claim 8, as well as other specific ligands described in the specification. As noted above, the definition of R embraces many ligands wherein (1) binding to a receptor may have no particular effect and/or (2) the receptor is yet unknown. The specification does not teach one of ordinary skill how to use compounds having such ligands. Therefore, one of ordinary skill would require undue experimentation in order to use these compounds commensurate with the scope of the claims.

The ligands that are enabled for the compounds would not all be enabled for the therapeutic method (claim 18). Oligosaccharides, such as the ones recited in claim 8 and particularly in multivalent systems, are known to have utility for the methods recited in claim 18. See review by Mammen et al (Angew. Chem. Int. Ed., 1998). However, one of ordinary skill would require undue experimentation to use the compounds having all the ligands embraced by

Art Unit: 1623

the claims, including the ligands particularly described in the specification, much less the ones with unknown receptors, for the therapeutic methods recited in claim 18.

With respect to the overall structure of the compounds, Tuzikov (of record) discusses the aggregation of these compounds and states that “tetraantennary design of the [compound] appears crucial for [aggregate] stability.” See last paragraph of page 150. Therefore, it appears that only the compounds wherein $m=4$ would have the requisite stability in aggregate form in order to be useful in the disclosed methods.

With regard to the subject matter deemed unenabled, the specification gives no guidance and presents no contradictory evidence.

Allowable Subject Matter

It appears that the claims are free of the art and that claims drawn to the enabled subject matter would be allowable. Regarding the indefiniteness of the limitation requiring aggregate formation, it is the opinion of the examiner that if the claims were limited to the enabled structure, this would define a reasonably homogeneous (with respect to aggregation and activity) set of compounds. Therefore, it would be expected that these compounds would have similar activity and aggregating behavior, so the limitation regarding aggregation would be unnecessary. This is only a suggestion, and Applicant may see other avenues for amending the claims, but the examiner does not see another (simple) way around this indefinite limitation. Another way would be a limitation regarding the environment wherein aggregates are formed, but it is not clear that this would be desirable or supported.

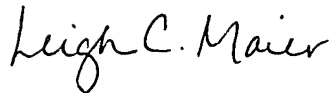
Art Unit: 1623

Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Thursday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Anna Jiang (571) 272-0627, may be contacted. The fax number for Group 1600, Art Unit 1623 is (571) 273-0627.

Visit the U.S. PTO's site on the World Wide Web at <http://www.uspto.gov>. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more.



Leigh C. Maier
Primary Examiner
December 23, 2005